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Personalised treatment packages for adults with a learning disability

Submission date
15/08/2022

Recruitment status
No longer recruiting

Registration date
16/11/2022

Overall study status
Ongoing

Last Edited
02/09/2025

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
The PETAL programme is designed to help adults with a learning disability who display aggression and those who support them work together to better understand and meet the person's individual needs. Although there are some issues that are commonly experienced, everyone is different, so a personalised approach is needed. 10-25% of adults with mild to severe learning disabilities display aggression. This behaviour affects their quality of life, leading to exclusion from social networks and community facilities including access to healthcare, placement breakdown, inability to stay in the family home, seclusion, overmedication etc.

A better understanding of the causes of an individual's aggressive behaviour and coproducing a personalised treatment package could make a significant difference to their quality of life. We work with adults with a learning disability and their families and paid carers to develop the PETAL therapy to address aggression and test if it works better than the current approaches available.

Who can participate?
Adults with learning disabilities and their carers (family or paid)

What does the study involve?
The PETAL therapy has four phases which are presented below:
1. Review the evidence about which psychosocial treatments for aggression work for adults with learning disabilities and for other client groups. We reviewed the manuals and how they are delivered.
2. Talk to adults with a learning disability who have good outcomes, and those with poorer outcomes, their family or paid carers and professionals. With those who reported things went well, we asked why they thought that was so. Where it did not go so well and explored what might have been more helpful.
3. Use routinely collected NHS data to assess how adults with a learning disability who display aggression respond to treatments. This enabled us to better understand what influences patient outcomes and to inform the design of PETAL therapy.
4. Use the findings from 1, 2 and 3, and worked with adults with learning disabilities, carers and professionals, to develop a personalised treatment package called PETAL therapy. We

developed a manual. We will train NHS staff in how to deliver the personalised treatment package and will test whether it is practical and acceptable, making changes if needed.
5. Find out, in a large trial, whether the personalised treatment package makes a positive difference to the health and quality of life of adults with a learning disability and how cost-effective it is.

What are the possible benefits and risks of participating?
There are a number of potential benefits to this study. At the moment, there is not a consistent approach to the management of aggression in adults with intellectual disabilities across the UK. If the PETAL therapy is effective, then it could be rolled out in all NHS services for adults with intellectual disabilities. Without evidence, we cannot convince health and social care services to change their usual practices. In addition, professionals, family, and paid carers would have gained special skills to better support adults with intellectual disabilities with aggressive challenging behaviour. There are no identified disadvantages to taking part in this research. Nonetheless, there is a time commitment to attend the PETAL therapy sessions over a period of 14 weeks. In addition, each research visit and interview might last for about 1 hour. If you find the PETAL therapy sessions, the research visits, or the interview too long, you may request a break.

Where is the study run from?
North London NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
October 2021 to September 2025

Who is funding the study?
National Institute for Health and Care Research (UK)

Who is the main contact?
Prof. Angela Hassiotis, a.hassiotis@ucl.ac.uk

Study website
https://www.ucl.ac.uk/psychiatry/research/epidemiology-and-applied-clinical-research-department/petal-programme-nihr-id-nihr200120

Contact information

Type(s)
Principal Investigator

Contact name
Prof Angela Hassiotis

ORCID ID
https://orcid.org/0000-0002-9800-3909

Contact details
Division of Psychiatry
Maple House
149 Tottenham Court Road
London

United Kingdom
W1T 7NF
+44 (0)2079743788
a.hassiotis@ucl.ac.uk

Type(s)
Public

Contact name
Ms Rebecca Griffiths

Contact details
Trial manager
Division of Psychiatry
University College London
149 Tottenham Court Road
London
United Kingdom
W1T 7NF
+44 (0)20 7679 9319
rebecca.griffiths@ucl.ac.uk

Type(s)
Scientific

Contact name
Dr Rachel Royston

ORCID ID
https://orcid.org/0000-0002-9901-2284

Contact details
Programme manager
Division of Psychiatry
University College London
149 Tottenham Court Road
London
United Kingdom
W1T 7NF
+44 (0)203 108 7815
r.royston@ucl.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
316749

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 316749, CPMS 53581

Study information

Scientific Title
Personalised treatment packages for adults with learning disabilities who display aggression in community settings: A cluster randomised controlled trial (PETAL therapy)

Acronym
PETAL therapy

Study objectives
The PETAL therapy alongside usual care significantly reduces aggressive challenging behaviour in adults with intellectual disability compared to usual care alone at 9 months post-randomisation

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 31/10/2022, Health and Care Research Wales (Castlebridge 4, Cardiff, CF11 9AB, Wales, UK; +44 (0)2920 230457; HCRW.approvals@wales.nhs.uk, Wales.REC7@wales.nhs.uk), ref: 22/WA/0267

Study design
Cluster randomized controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Community

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Intellectual disability

Interventions
Current interventions as of 03/01/2024:
We will randomise clusters (i.e., community learning disability services) to one of the two intervention arms. Intervention arms: The PETAL therapy alongside usual care. The PETAL therapy for aggressive challenging behaviour is a manualised personalised multicomponent package. It has been developed following a realist review of the evidence, qualitative interviews with people who had received an intervention for aggressive challenging behaviour, previous work by the co-applicant group and consultation with experts and experts by experience (i.e., family carers and people with intellectual disability). The PETAL therapy includes 7 modules and 2 review sessions that need to be completed within 14 weeks. The duration of each module can last up to 2 hours. The duration may differ depending on the person and their needs (i.e., some people may only be able to manage 40-minute sessions) and some people may need several breaks during the session. Sessions will be dyadic (the person with a learning disability and a family or paid carer). Control arm: Usual care alone. That means any care that is available within services across the UK.

Previous interventions:
We will randomise clusters (i.e., community learning disability services) to one of the two intervention arms. Intervention arms: The PETAL therapy alongside usual care. The PETAL therapy for aggressive challenging behaviour is a manualised personalised multicomponent package. It has been developed following a realist review of the evidence, qualitative interviews with people who had received an intervention for aggressive challenging behaviour, previous work by the co-applicant group and consultation with experts and experts by experience (i.e., family carers and people with intellectual disability). The PETAL therapy includes 7 modules and 2 review sessions that need to be completed within 14 weeks. The duration of each module can last up to 2 hours. The duration may differ depending on the person and their needs (i.e., some people may only be able to manage 40-minute sessions) and some people may need several breaks during the session. Sessions will be dyadic or triadic (with or without a carer or the adult with the intellectual disability). Control arm: Usual care alone. That means any care that is available within services across the UK.

Intervention Type
Behavioural

Primary outcome measure
Aggressive challenging behaviour measured using the Aberrant Behaviour Checklist irritability scale (ABC-I) at baseline, and 4 and 9 months follow up

Secondary outcome measures
Current secondary outcome measures as of 09/06/2023:

1. Episodes of physical aggression measured using the Behaviour Problems Inventory-short (BPI-S) at baseline, and 4 and 9 months follow up
2. Risk measured using the Threshold Assessment Grid (TAG) at baseline, and 4 and 9 months follow up
3. Family carer and paid carer confidence in managing aggression measured using the Difficult Behaviour Self-Efficacy scale at baseline, and 4 and 9 months follow up
4. Family carer wellbeing measured using the Warwick-Edinburgh Mental Wellbeing Scale (WEMWBS) at baseline, and 4 and 9 months follow up
5. Family carer Social Care Related Quality of Life measured using the Adult Social Care Outcomes Toolkit (ASCOT) at baseline, and 4 and 9 months follow up

6. Service use and medications measured using the Client Service Receipt Inventory (CSRI) at baseline, and 4 and 9 months follow up
7. Adult with intellectual disability health-related quality of life measured using the EuroQoL five Dimensions Scale (EQ-5D-3L) proxy and EuroQoL EQ-5D Learning disability (EQ-5D-LD) at baseline, and 4 and 9 months follow up
Other measures
1. Demographic data collected at baseline only
2. Clinical characteristics, including general ability of the person with an intellectual disability measured using the Adaptive Behaviour Scale-Short Version (ABS-S) at baseline only
3. Mental health status measured using the Moss Psychiatric Assessment Schedules (Moss-PAS (ID); formerly known as mini PAS-ADD), at baseline only
4. Adverse Events will be collected at 4 and 9 months follow up
5. Other therapies received by participant will be collected at baseline only
6. Staffing per team will be collected at baseline only

Previous secondary outcome measures:

1. Episodes of physical aggression measured using the Behaviour Problems Inventory-short (BPI-S) at baseline, and 4 and 9 months follow up
2. Mental health status measured using the Moss Psychiatric Assessment Schedules (Moss-PAS (ID); formerly known as mini PAS-ADD), at baseline, and 4 and 9 months follow up
3. Risk measured using the Threshold Assessment Grid (TAG) at baseline, and 4 and 9 months follow up
4. Family carer and paid carer confidence in managing aggression measured using the Difficult Behaviour Self-Efficacy scale at baseline, and 4 and 9 months follow up
5. Family carer wellbeing measured using the Warwick-Edinburgh Mental Wellbeing Scale (WEMWBS) at baseline, and 4 and 9 months follow up
6. Family carer Social Care Related Quality of Life measured using the Adult Social Care Outcomes Toolkit (ASCOT) at baseline, and 4 and 9 months follow up
7. Paid and family carer distress measured using the Kessler Psychological Distress Scale (K6) at baseline, and 4 and 9 months follow up
8. Service use and medications measured using the Client Service Receipt Inventory (CSRI) at baseline, and 4 and 9 months follow up
9. Adult with intellectual disability health-related quality of life measured using the EuroQoL five Dimensions Scale (EQ-5D) proxy at baseline, and 4 and 9 months follow up
10. Demographic data collected at baseline only
11. Clinical characteristics, including general ability of the person with an intellectual disability measured using the Adaptive Behaviour Scale-Short Version (ABS-S) at baseline, and 4 and 9 months follow up
12. Adverse Events measured using data recorded in the study log at baseline, 4 and 9 months follow up

Overall study start date
01/10/2021

Completion date
31/05/2026

Eligibility

Key inclusion criteria
Current inclusion criteria as of 09/06/2023:

1. Aged 18 years or over
2. Living in the community (e.g., residential care home, supported living, family home)
3. Registered with and/or eligible to receive support from community learning disabilities services
4. Incidents of physical aggression to people or property for at least 3 months. It is likely that people will have several additional comorbid behaviours such as verbal aggression, mental health problems, self-injury, stereotypies etc.
5. Consent to participate provided in keeping with UK capacity legislation or assent from family /nominated consultees for those lacking capacity
6. Family carer/other member able to understand English

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Previous inclusion criteria:

1. Aged 18 years old and over living in the community
2. Being under the care of a community intellectual disability service
3. Having a diagnosis of intellectual disability diagnosis by community intellectual disability service
4. Weekly incidents of physical aggression to people or property over 3 months
5. Consent to participate provided in keeping with UK capacity legislation or assent from their family/nominated consultees for those lacking capacity
6. Family carer able to understand English or questionnaire version available in the participant's language.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
410

Total final enrolment
204

Key exclusion criteria
Current exclusion criteria as of 09/06/2023:

1. Currently being an inpatient
2. Alcohol or drug dependent
3. Current enrolment in another clinical trial

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Previous exclusion criteria:

1. Not having an intellectual disability diagnosis
2. Alcohol or drug dependent
3. Current enrolment in another clinical trial

Date of first enrolment
26/01/2024

Date of final enrolment
31/07/2025

Locations

Countries of recruitment
England

Northern Ireland

Scotland

United Kingdom

Wales

Study participating centre
North London NHS Foundation Trust
4th Floor, East Wing
St. Pancras Hospital
4 St. Pancras Way
London
United Kingdom
NW1 0PE

Study participating centre
Devon Partnership NHS Trust
Wonford House Hospital
Dryden Road
Exeter
United Kingdom
EX2 5AF

Study participating centre
Norfolk Community Health and Care NHS Trust
Norwich Community Hospital
Bowthorpe Road
Norwich
United Kingdom
NR2 3TU

Study participating centre
South Eastern Health and Social Care Trust
Trust Headquarters Ulster Hospital
Upper Newtownards Road
Dundonald
Belfast
United Kingdom
BT16 1RH

Study participating centre
Western Health and Social Care Trust
Mdec Building
Altnagelvin Area Hospital Site
Glenshane Road
Londonderry
United Kingdom
BT47 6SB

Study participating centre
Southern Health and Social Care Trust
Southern Area College of Nursing
Craigavon Area Hospital
68 Lurgan Road, Portadown
Craigavon
United Kingdom
BT63 5QQ

Study participating centre
Hounslow and Richmond Community Healthcare NHS Trust
Thames House
180-194 High Street

Teddington
United Kingdom
TW11 8HU

Study participating centre
Lincolnshire Partnership NHS Foundation Trust
St George's
Long Leys Road
Lincoln
United Kingdom
LN1 1FS

Study participating centre
East London NHS Foundation Trust
Robert Dolan House
9 Alie Street
London
United Kingdom
E1 8DE

Study participating centre
Leicestershire Partnership NHS Trust
Room 100/110 Pen Lloyd Building
County Hall
Leicester Road
Leicester
United Kingdom
LE3 8RA

Study participating centre
Oxford Health NHS Foundation Trust
Littlemore Mental Health Centre
Sandford Road
Littlemore
Oxford
United Kingdom
OX4 4XN

Study participating centre
Bradford District Care Trust
Lynfield Mount Hospital

Heights Lane
Bradford
United Kingdom
BD9 6DP

Study participating centre
Yourhealthcare Community Interest Company
Hollyfield House
22 Hollyfield Road
Surbiton
United Kingdom
KT5 9AL

Study participating centre
North East London NHS Foundation Trust
West Wing
C E M E Centre
Marsh Way
Rainham
United Kingdom
RM13 8GQ

Study participating centre
Tees, Esk and Wear Valleys NHS Foundation Trust
Trust Headquarters
West Park Hospital
Edward Pease Way
Darlington
United Kingdom
DL2 2TS

Study participating centre
Berkshire Healthcare NHS Trust Headquarters
Skimped Hill Lane
Bracknell
United Kingdom
RG12 1LH

Study participating centre
Norfolk and Suffolk NHS Foundation Trust
County Hall

Martineau Lane
Norwich
United Kingdom
NR1 2DH

Study participating centre
Hertfordshire Partnership University NHS Foundation Trust
The Colonnades
Beaconsfield Close
Hatfield
United Kingdom
AL10 8YE

Study participating centre
Cambridgeshire and Peterborough NHS Foundation Trust
Elizabeth House,
Fulbourn Hospital
Fulbourn
Cambridge
United Kingdom
CB21 5EF

Study participating centre
Pennine Care NHS Foundation Trust
225 Old Street
Ashton-under-lyne
United Kingdom
OL6 7SR

Study participating centre
Birmingham Community Healthcare NHS Foundation Trust
3 Priestley Wharf
Holt Street
Birmingham Science Park, Aston
Birmingham
United Kingdom
B7 4BN

Study participating centre
Northamptonshire Healthcare NHS Foundation Trust
St Marys Hospital

77 London Road
Kettering
United Kingdom
NN15 7PW

Study participating centre
NHS South East London Icb - 72q
160 Tooley Street
London
United Kingdom
SE1 2TZ

Sponsor information

Organisation
North London NHS Foundation Trust

Sponsor details
Noclor NHS Research Office
Regis Road
London
England
United Kingdom
NW5 3EG
-
contact.noclor@nhs.net

Sponsor type
Hospital/treatment centre

Website
https://www.noclor.nhs.uk/

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research (NIHR) Programme Grant for Applied Research (PGfAR)

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in high-impact and peer-reviewed journal
Additional forms of dissemination of findings and engagement with the public and professional stakeholders include the following:
1. Contribution via publications to clinical guidelines, e.g., NICE
2. Presentations at scientific and professional, conferences and meetings on a local, national, and international level including those that address service user and parent/paid carer groups
3. A leaflet summarising the main results of the study will be disseminated to participants and services (sites) that participated in the study. We will also consider making short videos about the programme to enhance accessibility and increase audience reach. Dissemination will be in easy-read and plain English language to enhance accessibility. If family members of some participants have no understanding of English, we can provide a translated study summary.
4. The project website will contain information about the programme, links to published articles and progress reports
5. Newsletters will be produced and sent to all participants and participating services every six months
6. Social media such as Twitter will be used to increase programme visibility and to communicate with the wider scientific and clinical community
7. We will utilise the contacts and network of all co-applicants in order to access policymakers and other influencers and engage a wide audience
8. We will liaise with the communications departments of participating organisations to prepare briefings of the findings for policymakers and commissioners
9. A one-day dissemination event for the main results of the programme with invitees from a variety of stakeholders (carers, adults with intellectual disabilities), NHS England, clinicians, and commissioners of services

Intention to publish date
01/06/2026

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publicly available repository

IPD sharing plan summary

Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No